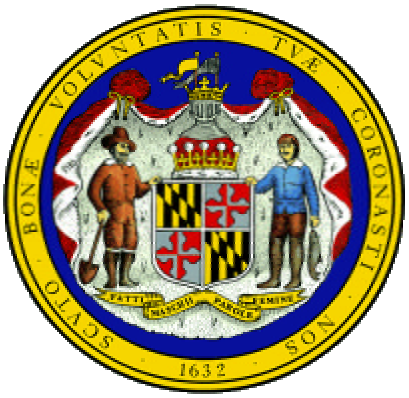
An Analysis and Evaluation of
Certificate of Need Regulation in Maryland

Cardiac Surgery and Therapeutic Catheterization Services

Summary of Public Comments and Staff Recommendations



MARYLAND HEALTH CARE COMMISSION

October 17, 2000

Donald E. Wilson, M.D., MACP
Chairman

John M. Colmers
Executive Director

Summary of Public Comments and Staff Recommendations on
An Analysis and Evaluation of Certificate of Need Regulation in Maryland
Working Paper: Cardiac Surgery and Therapeutic Catheterization Services

I. Introduction

The Commission's staff prepared the *Working Paper: Cardiac Surgery and Therapeutic Catheterization Services* as the basis for public comment on whether changes are needed with respect to the certificate of need (CON) regulation of cardiovascular services in Maryland. The current CON program regulates the availability, accessibility, cost, and quality of these services.

Several options for addressing the above characteristics were presented in the working paper. The Commission released the paper on August 18, 2000, and invited interested organizations and individuals to submit written comments on the working paper through September 18, 2000. The Commission received comments from the following:

1. Anne Arundel Medical Center (AAMC)
2. Carroll County General Hospital (CCGH)
3. Dimensions Healthcare Systems (DHS)
4. GBMC Healthcare (GBMC)
5. Holy Cross Hospital (HCH)
6. Johns Hopkins Medicine (JHM)
7. LifeBridge Health (LH)
8. MedStar Health (MH)
9. Montgomery County Commission on Health (MCCH)
10. Peninsula Regional Medical Center (PRMC)
11. St. Agnes HealthCare (SAH)
12. St. Joseph Medical Center (SJMC)
13. Southern Maryland Hospital (SMH)
14. Suburban Hospital (SH)
15. University of Maryland Medical Center (UMMC)

Copies of the full text of the comments were distributed to interested organizations and individuals by mail on September 21, 2000, and are available from the Commission upon request. Comments on this document are due on November 8, 2000.

II. Policy Options for Consideration

Major aspects of each option are listed below, followed by a summary of comments in support or opposition. A discussion of several key points precedes the recommendations of the staff.

A. Retain current CON regulation.

CON for new open heart surgery (OHS) service
No CON for new diagnostic cardiac catheterization service
CON regulation of therapeutic catheterization through on-site OHS backup
CON approval based on State health plan and CON criteria for review
CON withdrawal for failure to comply with conditions of approval
Noncompliance among criteria in future CON review
Monetary penalty for failure to provide information
Administrative order requiring information
Application to court for legal relief
Coordination among agencies

Support	Oppose
Establishment of open heart surgery (OHS)	
Supports a consistent approach to continued regulatory oversight through the CON process as a means to ensure adequate and equal access to health services across the state. Does not support continued CON regulation for OHS and removal of CON requirements for OB services. (HCH) The effects of deregulating cardiovascular services should be studied in a systematic way, with data to document that quality, access and pricing are stable or improved. Deregulation may have a negative impact on teaching and research. (JHM) A CON program is needed to protect against the establishment of programs with suboptimal volumes and/or the dilution of quality at existing programs. A strong CON program has not prevented the emergence of a competitive market for cardiac surgery services. HMOs have used RFP processes, case rate comparisons and competitive bidding to select a limited number of centers for specialized cardiac services. Managed care forces are actively operating to foster price competition and assure Maryland consumers reasonable rates. (LH) Scientific studies have demonstrated that high quality cardiac surgery services are associated with high volume programs. Conversely, low volume programs are associated with low quality services. By restricting the number of OHS programs, the State is able to maximize the likelihood that approved programs will have high volumes and thereby achieve the benefits of high volume programs. (PRMC) The guidelines put forth by the American College of Cardiology and the American Heart Association are relevant, appropriate and serve the best interests of the patients. The regulatory approach for cardiac surgery and therapeutic catheterizations should foster a collaborative environment among providers in order to improve outcomes. (UMMC)	The CON laws are a barrier to effective and timely treatment of heart disease. (AAMC) The CON options do not reflect the current competitive healthcare marketplace nor consider access from a patient choice perspective. (GBMC)

Support	Oppose
OHS backup for therapeutic catheterization	
Supports requirement at least until the Atlantic C-PORT study is concluded and the results are known. Preliminary results indicate that primary angioplasty can safely be performed without on-site cardiac surgery. If final results are consistent, support eliminating regulatory link between therapeutic catheterization services and on-site cardiac surgery backup. (CCGH) The safety and efficacy of angioplasty, with or without the presence of cardiac surgery backup, will become apparent after the research has been completed and there has been a review of the consensus of national specialty groups. The Maryland Health Care Commission may then make decisions about regulatory changes based on this consensus. (JHM) Supports requirement for on-site cardiac surgical backup. (LH) The co-location requirement is consistent with clinical guidelines of the American College of Cardiology, the American Heart Association and the Commission's Technical Advisory Committee on Cardiovascular Services and recognizes the inherent risks of angioplasty. (MH)	The need to "link" OHS and primary angiography no longer exists. (AAMC, GBMC) Until the American College of Cardiology revisits its 1993 guidelines, which state that PTCA should not be performed without on-site OHS backup, the link between OHS and PTCA effectively remains. (AAMC, GBMC) Whether, and how, such backup is provided should be determined by the providers, including clinicians, and the patients involved and the standard of practice in the community. (HCH) Questions the Commission's legal ability to prohibit hospitals from offering angioplasty services. Moreover, as the C-PORT Study has shown, there is no longer a legitimate clinical basis for permitting only those hospitals who offer cardiac surgery programs to offer angioplasty. (SH)
Review of availability	
A systematic process for planning health services is critical to ensure proper allocation of resources and service delivery where needed most. (HCH) Evidence of an inverse relationship between volume and quality presents a compelling reason for the State to promote and maintain large volume cardiac surgery and catheterization programs. Supports continuation of existing CON program, which concentrates volume in fewer centers through a managed growth strategy tied to need. (MH)	The existing CON program sets limits on the number of approvable OHS programs and considers applicants in opposition to other applicants and existing providers. It provides too many opportunities for parties opposed to such services to contest, slow down and defeat an application. (AAMC)

Support	Oppose
Review of accessibility	
The current system permits establishment of a State health plan that addresses a range of issues, for example, placing a premium on service to medically underserved communities. (DHS)	
Review of cost	
The overriding issue of staffing has cost, quality and access implications and must be a central characteristic of any review of provision of cardiac services. In the current environment, skilled health care professionals are one of the "scarce resources" that the State must allocate. Finding the staff to operate a facility is generally much harder than amassing the capital to build it. (LH) Staff shortages are driving up cost. Specialized services such as cardiac surgery and therapeutic catheterization services are the hardest hit because they require staff with advanced training and knowledge and are therefore more scarce and/or expensive to recruit and train. (MH)	No state other than Maryland operates under full rate regulation. Under the charge per case system, only hospitals with significant financial resources and the patient base to support OHS will be able to undertake the service. (AAMC)
Review of quality	
Supports a system of regular, timely measurement and evaluation of the quality of services provided by cardiac surgery programs, including inspections and outcomes review. Sanctions should include revocation of authority to operate. Primary responsibility for such a program should remain with MHCC, which should work in conjunction with the Office of Health Care Quality to design and implement such a program. (LH) Licensure is not a substitute for CON regulation. Licensure reviews quality retrospectively, i.e., after a program has already been established. The licensure approach fails to address whether facilities have the resources, expertise and commitment to initiate a successful program. (MH)	There are alternatives, including licensure, that can place limits on programs operating at levels determined to be, in fact, insufficient. CON does not, and never has, provided such an alternative. (AAMC) CON does not, and can not, actually monitor ongoing quality of care. Licensure is an ongoing effort that examines the quality of care actually provided. (GBMC)

Support (Review of quality – *Continued*)	**Oppose** (Review of quality – *Continued*)
The Certificate of Need program allows the State to improve quality of care without directly intervening with the operation of the hospitals. (PRMC)	

Discussion and Recommendations. The public comments raised a number of issues relevant to effective and timely treatment of heart disease, including the role of emergency transportation and pre-hospital treatment in a continuum of care, the experience of persons providing cardiac care, and the available evidence on prevention, diagnosis, and therapy from clinical trials. Addressing those issues, which involve CON- and non-CON-regulated services or actions, requires the concerted efforts of multiple organizations and individuals. **The staff recommends that the Commission continue to coordinate its planning and regulatory activities with other entities for the purpose of promoting affordable, accessible, high quality care for all residents of the state.**

As a matter of policy, the Commission's requirement that hospitals offering therapeutic catheterization services have on-site cardiac surgical backup is consistent with the joint guidelines of the American College of Cardiology (ACC) and the American Heart Association (AHA). The ACC/AHA guidelines note that major complications from angioplasty are unusual, with a very small percentage of patients needing emergency coronary bypass surgery when the angioplasty is unsuccessful. The *State Health Plan* includes provisions for exempting certain research projects from the policy requiring on-site backup. **The staff recommends continuation of the limited exemption for primary angioplasty performed in hospitals participating in the C-PORT project.** Recognizing that these cases comprise a relatively small number in comparison to elective procedures, **the staff also recommends a research project regarding cardiac surgical support for specific groups of patients receiving elective angioplasty.** The project would be a component of a recommended advisory committee on the assessment of outcomes.

Changes to CON and other areas of the health care regulatory system in Maryland may affect the ability of the Health Services Cost Review Commission (HSCRC) to control hospital costs. In comments on the *White Paper: Policy Issues in Planning and Regulating Open Heart Surgery Services in Maryland*, the HSCRC expressed strong support for promoting competition for open heart surgery services, balanced against changes in volume and quality-of-care concerns. As suggested by the HSCRC, **the staff recommends that the MHCC and HSCRC monitor changes in market demand and referral patterns as a result of new or expanded OHS services that may affect Maryland's Medicare waiver.**

Using data from discharge abstracts, the Commission can track surgical volumes and monitor institutions that perform less than a specified number of cases annually. In-hospital mortality rates may also be used as an indicator of potential problems with the quality of care provided. To assure that the methods of adjusting for risks are adequate, **the staff recommends that the Commission establish an Advisory Committee on Outcome Assessment in Cardiovascular Care.** The committee would review available models of measuring outcomes, develop an agenda on researching the organization of services to improve outcomes, and develop recommendations for an ongoing process to assess outcomes of cardiovascular care.

B. Retain and strengthen CON regulation.

Retain:

CON for new open heart surgery (OHS) service

Strengthen:

CON for new diagnostic or therapeutic cardiac catheterization service

~~No CON for new diagnostic cardiac catheterization service~~

~~CON regulation of therapeutic catheterization through on-site OHS backup~~

Retain:

CON approval based on State health plan and CON criteria for review
CON withdrawal for failure to comply with conditions of approval
Noncompliance among criteria in future CON review
Monetary penalty for failure to provide information
Administrative order requiring information
Application to court for legal relief

Strengthen:

Add: Loss of CON for failure to meet established standards for quality
Public notification of violation or enforcement
Civil fine equal to charges for services provided in violation of CON
Recovery of costs for services prohibited
Refund of collected charges required upon request

Support	**Oppose**
Regulation of cardiac catheterization	
Reinstatement of CON for cardiac catheterization is not warranted provided that the co-location requirement (on-site cardiac surgery backup for therapeutic cardiac catheterization services) is maintained. Absent the co-location requirement, supports the inclusion of angioplasty under CON coverage. (MH) Supports retaining CON for open heart surgery services and strengthening CON regulation of cardiac catheterization. Research continues to reinforce the correlation of high volume centers and low mortality rates. Specialized cardiac services depend on highly specialized health care teams that include perfusionists, critical care nurses, cath lab technicians, cath lab and OR nurses, and respiratory therapists. (SJMC)	There would be little advantage or harm from extending the CON process to cardiac catheterization. Virtually every hospital for which a program would be an option already has one. Furthermore, most hospitals that have programs could avoid CON coverage through the use of a various exemptions in the CON law. (DHS) Supports the continued exemption from CON regulation of cardiac catheterization laboratories and medical equipment. Much of what cardiac catheterization laboratories do is done on a very efficient outpatient basis. Further, most hospitals already have cardiac cath labs. Please note that the CON laws do not regulate what can be done in any other type of laboratory. (HCH)

Support	Oppose
Withdrawal of CON for noncompliance	
Supports granting the appropriate State agency the authority to remove a CON if the required services volumes are not met. (MCCH)	Discussion of the option assumes that the Commission will continue to treat new applicants differently than existing programs in regard to cessation if minimum volumes are not met. In earlier comments, the legality and fairness of this mandatory approach are questioned, and it is suggested instead that a preference be given to a hospital that made a voluntary commitment to cease its program if it did not attain minimum volumes. (HCH)
Additional sanctions	
	Adding sanctions would severely punish hospitals that might provide therapeutic catheterization to a patient in need of the service. (AAMC) Oppose the granting of authority to enforce the terms of a CON if it were restricted to cardiac surgery. There is no indication that a compliance problem exists. (DHS) If a program were beginning to make progress, the imposition of any sanction short of closing the program would likely delay the achievement of success. The involuntary closure of a program which otherwise was meeting acceptable quality standards would be inappropriate. (DHS) Although there is a statistical association between high volumes and lower mortality in a cardiac surgery program, it does not mean that any given low volume program is harming its patients. Existing mechanisms can take action against any program that is harming patients. The Commission is not equipped to make informed judgements as to whether a given program is achieving acceptable clinical results. (DHS)

Discussion and Recommendations. The staff recognizes that cardiac services are changing, and maintaining the status quo with regard to regulating them is not appropriate. For example, the current rule of using volume as the principal indicator of quality of care must be examined. Additionally, the clinical community, through its participation in a recommended research project, should assist in establishing appropriate protocols and evaluating whether the link between angioplasty and open heart surgery should remain. **The staff recommends that the Commission should establish quality standards for cardiac surgery programs, using the evidence-based recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care.**

If a program fails to meet the standards adopted by the Commission, the program should be given a period of time to remedy the failure. If the noncompliance continues after the period for remedy, the Commission should withdraw the CON and the authority to operate the program. The recommended sanction should extend to both new and existing programs, including those programs that predate the specific statutory provision concerning open heart surgery. The staff recommends no other additional sanctions.

C. Retain but restrict CON regulation.

Retain:

CON for new open heart surgery (OHS) service
No CON for new diagnostic cardiac catheterization service
CON regulation of therapeutic catheterization through on-site OHS backup
CON approval based on State health plan and CON criteria for review
CON withdrawal for failure to comply with conditions of approval
Noncompliance among criteria in future CON review
Monetary penalty for failure to provide information
Administrative order requiring information
Application to court for legal relief
Coordination among agencies

Restrict:

CON and plan limited to availability and geographic accessibility
Elimination of CON authority to regulate quality or financial access

Support	**Oppose**
CON review of availability and geographic access only	
Deregulation of cardiovascular services has not been studied systematically. Limiting the authority of the CON program to projections of need based on geographic access and distribution of services is clearly appropriate. (MCCH)	*Review of availability* The existing CON program sets limits on the number of approvable OHS programs and considers applicants in opposition to other applicants and existing providers. A CON program that considered, instead of need projections, the needs and capabilities of each applicant individually and assessed the applicant's ability to provide the financial and clinical support for the proposed program might be plausible. (AAMC) The CON process for OHS could be restructured to focus on each hospital's unique situation. However, the entirety of the CON process would have to be revisited as long as the CON process requires consideration of "need" in any other than an institutional sense, or limits the number of providers, or requires consideration of the impact on existing providers. (GBMC)

Support	Oppose
	Review of availability – Continued The current regulatory system simply protects existing providers from competition. Cardiac surgery should no longer be subject to the type of CON process that exists in Maryland. On the other hand, cardiac surgery should not be completely deregulated. A "middle ground" regulatory approach would be to eliminate the requirement that a hospital proposing to develop a cardiac surgery program make a quantitative showing that the proposed program is "needed." Under this model, most of the non-need related approval policies and standards would be retained. If further analysis demonstrates that "complete deregulation" has not resulted in a proliferation of low-volume programs in other states, may recommend that this approach be adopted in Maryland. (SH) Does not favor the complete deregulation of angioplasty, assuming that the Commission has the legal authority to require that a hospital obtain a CON before providing angioplasty. Unqualified providers may offer angioplasty if all approval standards are removed. Any hospital that can meet appropriate standards should be allowed to develop this service. The entry requirements, however, should not include the quantitative need showing. However, a hospital otherwise demonstrating the clinical ability to initiate angioplasty services should not be able to provide the service if this would reduce volumes at existing programs below appropriate minimums. (SH) A hospital that cannot offer OHS services cannot compete for managed care business. As long as the CON law makes open heart a franchise, the CON law will be used to curtail competition. (GBMC)

Support	Oppose
	Review of availability – Continued If a licensure approach based on performance standards is not viewed as a viable option, supports development of a CON exemption model. This model would allow providers proposing new OHS programs to justify their position in an expedited review not against need projections, but according to exemption criteria of consistency with SHP, promoting cost-effective services, and public interest. (SAH) *Limitation of review* The value of the CON model of regulation is the fact that it involves a public and comprehensive assessment of need that balances quality, access and cost issues in determining need for new programs within a single agency. This benefit would be lost if regulation of specialized cardiac services is split among several regulatory bodies, as described. (MH) The existing CON process gives competitive institutions incentives to innovate their programs in socially desirable ways, as by requiring a commitment to outreach by the use of the CON as leverage. A minimal CON program focusing primarily on need and capacity would forfeit most of this leverage and with it most of the ability to shape the system. (DHS)
Transfer of review of quality	
Supports transferring responsibility for quality of care issues to the appropriate State agencies. (MCCH) CON does not now regulate ongoing quality. Assigning the review of quality of existing OHS programs to licensure would be appropriate and would not be a diminution of the MHCC's authority. In addition, licensure could review the ongoing quality of therapeutic cardiac catheterization services. The MHCC would continue to have a role in quality reporting under its report card and other data report activities. (HCH)	Support retaining current regulation. (LH, MH)

Support	Oppose
Transfer of review of financial access	
Supports transferring responsibility for cost issues to the appropriate State agencies. (MCCH)	Close coordination between the various government agencies, particularly the MHCC and the HSCRC, remains essential without any change in agency authorities. (HCH) Support retaining current regulation. (LH, MH)

Discussion and Recommendations. In 1999, a change in the law resulted in the transfer of health planning functions for non-CON-related entities to the Department of Health and Mental Hygiene. The statewide plan developed and adopted by the Commission focuses on CON-regulated services. The current law also provides for the development and adoption of an institution-specific plan, to be used in conjunction with the State health plan in reviewing certificate of need applications. The hospital-specific plan is intended to address, among other issues, migration patterns and population data, quality of care, and health care needs for the area served by each hospital. More than one hospital may be in the service area in which residents seek cardiac care, a reflection of payer and physician affiliations as well as patient choice. Given the competition for patients and limited resources, such as specialized staff and reimbursement, a focus on institutional planning should not preclude an evaluation of a population's needs and the distribution of services to meet those needs. **The staff recommends that the Commission continue to review the availability, accessibility, cost, and quality of cardiac surgery services through the CON program. The Commission should also continue to coordinate the exercise of its functions with the Department of Health and Mental Hygiene and the Health Services Cost Review Commission, as required by law.**

D. Eliminate CON regulation.

Eliminate:

- CON for new open heart surgery (OHS) service
- CON regulation of therapeutic catheterization through on-site OHS backup
- CON approval based on State health plan and CON criteria for review
- CON withdrawal for failure to comply with conditions of approval
- Noncompliance among criteria in future CON review

Retain:

- No CON for new diagnostic cardiac catheterization service
- State health plan to assess geographic access
- Collection and analysis of data
- System to measure performance of hospitals
- Monetary penalty for failure to provide information
- Administrative order requiring information
- Application to court for legal relief
- Coordination among agencies

Add:

- Licensure with performance standards

Support	Oppose
Elimination of CON regulation	
Licensure with performance standards The Commission should be consistent in its philosophy concerning the regulation of health care services. Favors a licensure approach coupled with performance standards as the preferred mechanism to regulate Maryland's health care services. Angioplasty should be de-coupled from open heart surgery, that is, on-site backup with open heart surgery should not be required. Performance standards should be established for hospitals that perform primary and elective angioplasty. Hospitals which currently have open heart surgery services should be required to cooperate with those who do not by surgically backing up angioplasty procedures. A licensure process should be developed whereby hospitals who successfully perform angioplasty for a designated period of time can move further into the full continuum by establishing an on-site open heart program. The regulatory/licensure standards should include continuum of care requirements for each new and old OHS hospital. (SAH)	Does not support elimination of CON regulation of OHS; supports revision of the way OHS is regulated by CON. Supports cessation of CON regulation of therapeutic catheterization services. (HCH)
Review of cost The HSCRC has proven itself quite capable of limiting increases in cost in Maryland over an extended period of time. Quality of care programs already exist and could be strengthened. Access and fairness will be improved if new OHS programs are added. (AAMC) The HSCRC has both the duty and the proven ability to ensure that Maryland's patients pay reasonable charges for care. (GBMC) Cost containment of cardiovascular services is already being achieved through hospital rate regulation and managed care delivery systems. The only costs directly affected by CON regulation are capital costs, which represent a small faction of the total costs of a cardiac surgery service. (SMH)	If the CON process were repealed, hospitals would lose regulatory incentive for outreach to underserved communities. (DHS)

Support (CON elimination – *Continued*)	**Oppose** (CON elimination – *Continued*)
Review of quality Supports reporting requirements and the development of specific standards for quality of cardiovascular services. The issue is the quality of, and appropriate access to, affordable cardiac care. Licensure provides a better approach to both than CON, and is the preferred alternative. Licensure could be structured to provide appropriate regulatory oversight by establishing standards for entry for the service as well as regular monitoring. Ongoing licensure review would be based upon volume standards, mortality standards, and the guidelines for quality of care developed by organizations such as the American College of Cardiology, the American Heart Association and the American College of Surgeons. (GBMC) Hospitals should be encouraged, or even required as part of the OHS license, to provide community education and health programs on cardiac care, provide outreach programs for underserved populations in the hospital's area, have emergency room capability to minimize time to initiate appropriate treatment, provide angioplasty capability through experienced interventional cardiologists, and demonstrate sufficient patient volumes to assure quality of care on an ongoing basis. (GBMC) Whether through licensure, heavily revised CON, or an entirely new program to encourage cardiac care, the new program would require any hospital that offered OHS to: provide community education and health programs on cardiac care, provide outreach programs for underserved populations in the hospital's area, provide emergency room capability to minimize time to initiate appropriate treatment, provide angioplasty capability through experienced interventional cardiologists on staff, and demonstrate sufficient patient volumes from its own patient population to assure quality of care. (AAMC)	Under the current State law, the licensing authority generally cedes its review function to the Joint Commission on Accreditation of Healthcare Organizations, a private standards organization. The Office of Health Care Quality, which does not now routinely survey acute hospital services for compliance, will have to commence surveying at least cardiac surgery programs. The adoption of a licensure system is likely to delay the approval of new programs. (DHS) Unlike the Commission, the Office of Health Care Quality is not charged by the Legislature to do such things as analyze access to services or evaluate cost effectiveness and economic, social and health care trends on a regular basis. (DHS) While "enhanced licensure" may address some quality concerns, it does not address issues of access and cost. The licensure approach for regulating open heart surgery programs is relatively new.(MH) Rather than being substitutes for each other, licensure and Certificate of Need programs can be complementary. There is no reason why the State needs to eliminate the Certificate of Need program in order to implement a licensure program. Both programs operate to assure quality in very different ways. Supports the adoption of both to maintain the highest quality cardiac surgery services for the residents of Maryland. (PRMC)

Support	Oppose
Assessment of geographic access in statewide plan	
Allowing competition among providers would afford patients a greater range of choice of services and would increase access to these services. The Commission would be able to monitor access and serve as a reference on this issue to the health care community. (SMH)	
Collection and analysis of data	
Supports data reporting and the development of specific standards for reviewing quality of cardiovascular services. (AAMC, GBMC) The proposal for a consortium to collect data and monitor outcomes would require less involvement of the State in the operational details of a program, and would provide a mechanism to track the quality of a program and to encourage continuous quality improvement in the program. The consortium would also not require the adversarial contested case hearings that an attempt to impose sanctions would call for. (DHS) Strongly supports development of an independent oversight group with participation by all existing programs, to share data and protocols. (JHM) Strongly supports establishment of the Advisory Committee on Outcome Assessment in Cardiovascular Care. Supports as well the concept of expanding MHCC authority to monitor existing programs. (LH) Supports development of a continuous improvement model for specialized cardiac services in Maryland, similar to The Northern New England Cardiovascular Disease Study Group, a voluntary research consortium composed of physicians, researchers, and hospital administrators in Maine, New Hampshire and Vermont. There is value in a voluntary, cooperative effort to collect, report and share clinical outcome and program performance data among programs. This effort, unlike a formal licensure regulatory approach, should be voluntary, collaborative and non-punitive. (MH)	

Support	Oppose
Data – Continued Regulatory oversight of cardiac surgery should be focused on establishing and enforcing appropriate standards for quality of care. This oversight could be conducted by the Commission or by the Office of Health Care Quality. Quality-of-care standards for cardiac surgery are now well-defined by standards such as the "Guidelines and Indications for Coronary Artery Bypass Graft Surgery," approved by the American College of Cardiology and the American Heart Association, and the "Guidelines for Standards in Cardiac Surgery," approved by the American College of Surgeons. In developing any cardiovascular quality-of-care standards, the Commission should consider these standards and guidelines. Data collection and outcomes reporting would allow the Commission to monitor the quality of care being provided. (SMH)	

Discussion and Recommendations. The staff believes that a wholesale elimination of CON regulation of cardiac services would be premature. As part of the process to develop and adopt implementing regulations, the staff has recommended changes to specific policies and standards in the statewide plan used to review CON applications. Implementation and evaluation of those changes should precede any further changes to CON that may affect the ability of other areas of the health care regulatory system in Maryland to perform their functions effectively. **The staff recommends continued regulatory oversight through the CON program, with the appointment of an advisory committee to make recommendations to the Commission on key issues.**

III. Conclusion and Summary of Recommendations

In October 1999, the Maryland Health Resources Planning Commission and the Health Care Access and Cost Commission were consolidated to form the Maryland Health Care Commission. As part of an examination of certificate of need, the Commission's staff considered a range of options, from retaining the current CON regulation of availability, accessibility, cost, and quality of open heart surgery services, as required by law, to eliminating CON regulation of these services. At this time, the staff does not recommend wholesale change in the authority of the CON program. The staff has recommended a number of administrative changes that the Commission can undertake under its current statutory authority. A recommended expansion of the sanctions available to the Commission to encourage quality of care will require a change in the statute.

Proposed Administrative Changes

Recommendation 1. The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care.

The committee would review available models of measuring outcomes, develop an agenda on researching the organization of services to improve outcomes, and develop recommendations for an ongoing process to assess outcomes of cardiovascular care.

Recommendation 2. The Commission should use a well-designed research project to investigate cardiac surgical support for specific groups of patients receiving elective angioplasty.

The research project would be a component of the Advisory Committee on Outcome Assessment in Cardiovascular Care. The limited exemption for primary angioplasty performed in hospitals participating in the G-PORT project would continue; however, these cases comprise a relatively small number in comparison to elective procedures.

Recommendation 3. The Commission should continue to coordinate its planning and regulatory activities with other entities for the purpose of promoting affordable, accessible, high quality care for all residents of the state. The MHCC and HSCRC should monitor changes in market demand and referral patterns as a result of new or expanded open heart surgery services that may affect Maryland's Medicare waiver.

Promoting competition for open heart surgery services should be balanced against concerns about quality of care. The State must also consider a number of factors that affect access to effective and timely treatment of heart disease. Providing financial and geographic access to quality health care services at a reasonable cost for all residents of Maryland will require the efforts of multiple organizations and individuals.

Recommendation 4. The Commission should continue its regulatory oversight of open heart surgery services through the CON program.

The Commission is also responsible for developing and implementing a system to comparatively evaluate the outcomes and performance of hospitals on an objective basis, and annually publishing the summary findings of the evaluation. Creating specific standards for cardiovascular services may increase the effective use of information about hospitals that provide those services.

Recommended Statutory Change

Recommendation 5. The Commission should withdraw the CON and authority to operate a new or existing cardiac surgery program for failure to meet adopted standards for quality of care within a specified period.

The Commission should establish quality standards for cardiac surgery programs, using the evidence-based recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care. If a program fails to meet the standards adopted by the Commission, the program should be given a period of time to remedy the failure. If the noncompliance continues after the period for remedy, the Commission should withdraw the CON and the authority to operate the program. The sanction should apply to both new and existing programs, including those programs that predate the specific statutory provision concerning open heart surgery.